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In re Application of PLATZ ET AL

Application Number 08/246034 Filed 8/29/02

Paper No. #19

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703-486-1150
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(12) **United States Patent**
Platz et al.

(10) **Patent No.: US 6,797,258 B2**
(45) **Date of Patent: Sep. 28, 2004**

(54) **COMPOSITIONS AND METHODS FOR THE PULMONARY DELIVERY OF AEROSOLIZED MACROMOLECULES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 08/423,515, filed on Apr. 14, 1995, and a continuation-in-part of application No. 08/417,507, filed on Apr. 4, 1995, now abandoned, and a continuation-in-part of application No. 08/383,475, filed on Feb. 1, 1995, now abandoned, which is a continuation-in-part of application No. 08/232,849, filed on Apr. 25, 1994, now Pat. No. 5,607,915, and a continuation-in-part of application No. 08/313,707, filed on Sep. 27, 1994, now abandoned, and a continuation-in-part of application No. 08/309,691, filed on Sep. 21, 1994, now Pat. No. 5,785,049, and a continuation-in-part of application No. 08/246,034, filed on May 18, 1994, now abandoned, which is a continuation of application No. 08/044,358, filed on Apr. 7, 1993, now abandoned, which is a continuation-in-part of application No. 07/910,048, filed on Jul. 8, 1992, now Pat. No. 5,458,135.

(51) **Int. Cl.**[7] **A61K 9/00**; A61K 9/12; A61K 9/14

(52) **U.S. Cl.** **424/45**; 424/46; 424/489; 424/499; 514/15; 514/17; 514/2; 128/200.14

(58) **Field of Search** 424/45, 46, 489, 424/499; 514/15, 17, 2, 18; 128/200.14

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(57) **ABSTRACT**

According to the subject invention, dispersible dry powder pharmaceutical-based compositions are provided, including methods for their manufacture and dry powder dispersion devices. A dispersible dry powder pharmaceutical-based composition is one having a moisture content of less than about 10% by weight (% w) water, usually below about 5% w and preferably less than about 3% w; a particle size of about 1.0–5.0 μm mass median diameter (MMD), usually 1.0–4.0 μm MMD, and preferably 1.0–3.0 μm MMD; a delivered dose of about >30%, usually >40%, preferably >50%, and most preferred >60%; and an aerosol particle size distribution of about 1.0–5.0 μm mass median aerodynamic diameter (MMAD), usually 1.5–4.5 μm MMAD, and preferably 1.5–4.0 μm MMAD. Such compositions are of pharmaceutical grade purity.

22 Claims, No Drawings